IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TIMOTHY J. WONNELL, Derivatively on Behalf of Nominal Defendant ATHENEX, INC., Plaintiff, v. JOHNSON Y.N. LAU, KIM CAMPBELL, STEPHANIE DAVIS, MANSON FOK, JORDAN KANFER, ROBERT J. SPIEGEL, M.D., BENSON TSANG, JOHN M. VIERLING, M.D. AND JINN WU, Defendants, And ATHENEX, INC., Nominal Defendant.	Case No. JURY TRIAL DEMANDED

VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiff Timothy J. Wonnell ("Plaintiff"), by and through his undersigned attorneys, brings this derivative complaint for the benefit of nominal defendant, Athenex, Inc. ("Athenex" or the "Company"), against its Board of Directors (the "Board") and certain of its executive officers seeking to remedy defendants' breaches of fiduciary duties and violations of federal law. Plaintiff's allegations are based upon his personal knowledge as to himself and his own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff's counsel, including a review of publicly available information, including filings by Athenex with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

NATURE AND SUMMARY OF THE ACTION

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Athenex, Inc.'s directors and officers in their management and control of the Company from August 7, 2019 to the present ("Relevant Period").

2. The Company was founded in 2003, and according to its recent public statements, is a "global clinical stage biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer." The Company is "organized around three platforms, including an Oncology Innovation Platform, a Commercial Platform, and a Global Supply Chain Platform." One of the Company's main drug candidates is an oral paclitaxel and encequidar for the treatment of metastatic breast cancer.

3. On August 7, 2019, the Company announced topline data showing that oral paclitaxel and encequidar met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase 3 pivotal study in metastatic breast cancer. In this release, the Company stated that it intended to seek a pre-New Drug Application ("NDA") meeting with the U.S. Food and Drug Administration ("FDA") and would "be preparing our NDA submission as soon as possible." Over the next several months, the Company continued to laud their Phase 3 study of oral paclitaxel plus encequidar.

4. On September 1, 2020, the Company announced that the FDA had accepted for filing the Company's NDA for Oral Paclitaxel and Encequidar in metastatic breast cancer with priority review.[1] In this release, the Company announced that the FDA had set a target action date

[1] https://ir.athenex.com/news-releases/news-release-details/athenex-announces-fdaacceptance-filing-us-nda-oral-paclitaxel.

of February 28, 2021 for the Company's NDA, and that "the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application."

5. Then, on December 9, 2020, the Company announced that it had presented updated Phase 3 data on survival and tolerability associated with Oral Paclitaxel and Encequidar in patients with metastatic breast cancer.[2] The Company announced that it had presented this Phase 3 data at the 2020 San Antonio Breast Cancer Symposium, and that the data "demonstrat[ed] clinical benefits in efficacy and tolerability of oral paclitaxel versus IVP in patents with metastatic breast cancer . . . . The findings further support the superiority of increased ORR [objective response rate] observed with oral paclitaxel." In this announcement, Defendant Johnson Y.N. Lau ("Lau"), Athenex's Chairman and Chief Executive Officer ("CEO"), stated:

> Having previously presented superior efficacy on overall response rate and favorable tolerability versus IV paclitaxel at [San Antonio Breast Cancer Symposium] 2019, it is gratifying to report that our pivotal Phase 3 trial continues to show sustained efficacy and manageable adverse events with oral paclitaxel and encequidar . . . . The updated Phase 3 PFS and OS data further support the clinical rationale for oral paclitaxel as an efficacious and tolerable treatment option for people living with metastatic breast cancer.

6. Defendants caused the Company to make false and/or misleading statements concerning: (i) the data included in the Oral Paclitaxel plus Encequidar NDA presented a safety risk to patients in terms of an increase in neutropenia-related sequalae; (ii) the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by BICR; (iii) the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR; (iv) that the Company's Phase 3 study that was used to file the NDA was inadequate and not well-conducted in a patient population with metastatic breast cancer

[2] https://ir.athenex.com/news-releases/news-release-details/athenex-presents-updatedphase-3-data-survival-and-tolerability.

representative of the U.S. population, such that the FDA would recommend a new such clinical trial; (v) as a result, it was foreseeable that the FDA would not approve the Company's NDA in its current form; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

7. Before the markets opened on March 1, 2021, the Company issued a press release entitled *Athenex Receives FDA Complete Response Letter for Oral Paclitaxel Plus Encequidar for the Treatment of Metastatic Breast Cancer*.[3] In this release, the Company noted that the "FDA Issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form." This release further provided that "[i]n the CRL, the FDA indicated its concern of safety risk to patients in terms of an increase in neutropenia-related sequalae on the Oral Paclitaxel arm compared with the IV paclitaxel arm."

8. In this March 1, 2021 press release, the Company further stated that the "FDA also expressed concerns regarding the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by blinded independent centra review (BICR). The [FDA] stated that the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR."

9. Last, in this release, the Company wrote that the FDA "recommended that Athenex conduct a new adequate and well-conducted clinical trial in a patient population with metastatic breast cancer representative of the population of the U.S. The [FDA] determined that additional risk mitigation strategies to improve toxicity, which may involve dose optimization and/or exclusion of patients deemed to be at a higher risk of toxicity, are required to support potential

[3] https://ir.athenex.com/news-releases/news-release-details/athenex-receives-fda-completeresponse-letter-oral-paclitaxel.

approval of the NDA."

10. On this news, the price of Athenex's shares plummeted from their February 26, 2021 closing price of $12.10 per share to a March 1, 2021 close of just $5.46 each.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 in that this Complaint alleges a violation of federal law. This Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. § 1367(a). This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

12. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because a substantial portion of the transactions and wrongs complained of herein occurred in this District, and the Defendants have received substantial compensation in this district by engaging in numerous activities that had an effect in this District.

13. The Company's forum selection clause also states:

> **Section 6.1 Forum**. Unless a majority of the Board of Directors, acting on behalf of the Corporation, consents in writing to the selection of an alternative forum (which consent may be given at any time, including during the pendency of litigation), the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court located within the State of Delaware or, if no court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Corporation, (b) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (c) any action asserting a claim against the Corporation or any of its current or former directors, officers or other employees arising pursuant to any provision of the DGCL, the Certificate of Incorporation or these Bylaws (in each case, as may be amended from time to time) or (d) any action asserting a claim against the Corporation or any of its current or former directors, officers or other employees governed by the internal affairs doctrine of the State of Delaware, in all cases subject to the court's having personal jurisdiction over all indispensable parties named as defendants.

PARTIES

Plaintiff

14. ***Plaintiff Timothy J. Wonnell*** purchased shares of Athenex stock in March of 2018 and continues to hold his Athenex stock currently.

Nominal Defendant

15. ***Nominal Defendant Athenex*** is a global clinical stage biopharmaceutical company attempting to become a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer. Shares of Athenex common stock trade on the NASDAQ stock exchange under the ticker "ATNX." The Company's headquarters are located at 1001 Main Street, Suite 600, Buffalo, New York 14203. Athenex is incorporated under the laws of the State of Delaware.

Director Defendants

16. ***Defendant Johnson Y.N. Lau*** ("Lau") is the Company's Chief Executive Officer ("CEO") and Chairman of the Company's Board of Directors (the "Board"). Defendant Lau has served as the Chairman of the Board since its inception and assumed the role of CEO in mid-2011.

17. ***Defendant Kim Campbell*** ("Campbell") is a member of the Board.

18. ***Defendant Stephanie Davis*** ("Davis") is a member of the Board.

19. ***Defendant Manson Fok*** ("Fok") is a member of the Board. Defendant Fok is a member of the Scientific & Products Committee.

20. ***Defendant Jordan Kanfer*** ("Kanfer") is a member of the Board. Defendant Kanfer is also a member of the Board's Audit and Risk Management Committee; Compensation Committee; and Finance Committee.

21. ***Defendant Robert J. Spiegel*** ("Spiegel") is a member of the Board. Defendant

Spiegel is the Chair of the Scientific & Products Committee.

22. ***Defendant Benson Tsang*** ("Tsang") is a member of the Board. Defendant Tsang is also a member of the Board's Audit and Risk Management Committee; Compensation Committee; and Finance Committee.

23. ***Defendant John M. Vierling, M.D.*** ("Vierling") is a member of the Board. Defendant Vierling is also a member of the Scientific & Products Committee.

24. ***Defendant Jinn Wu*** ("Wu") is a member of the Board. Defendant Wu is a member of the Board's Audit and Risk Management Committee and Finance Committee. Defendant Wu is a member of the Scientific & Products Committee.

25. Defendants Lau, Campbell, Davis, Fok, Kanfer, Spiegel, Tsang, Vierling and Wu are herein referred to as the "Director Defendants." Because of their positions with the Company, they possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Director Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

Officer Defendants

26. ***Defendant Rudolf Kwan*** ("Kwan") is the Company's Chief Medical Officer.

27. ***Defendant Timothy Cook*** ("Cook") is the Company's Senior Vice President, Global Oncology, having joined the Company in that role in July 2018.

28. The Director Defendants and Defendants Kwan and Cook are collectively referred to herein as "Defendants".

THE AUDIT COMMITTEE CHARTER

29. The Audit Committee is responsible to monitor the accuracy of all public filings concerning the financial statements of the Company and to ensure the accuracy of the financial statements themselves, and to ensure the integrity of the Company's internal controls.

30. The purpose of the Audit is to assist the Board in its oversight of the quality and integrity of the Company's financial statements, the Company's compliance with legal and regulatory requirements, and the qualifications, performance and independence of the external auditors.

THE SCIENTIFIC AND PRODUCTS COMMITTEE

31. The Scientific and Products Committee consists of Defendants Spiegel, Fok, Vierling and Wu. The Scientific and Products Committee met 2 times during 2020 fiscal year. In addition to any duties and responsibilities assigned to the committee from time to time by our Board, the Scientific and Products Committee has the following responsibilities:

- Review, evaluate and advise the Board and management on the strategy, objectives and priorities, as well as robustness and quality, of the Company's current and planned R&D programs and technology initiatives, with respect to their impact on the Company's potential performance, growth and competitive position;

- Identify and provide the Board with strategic advice on significant emerging science and technology issues, innovations and trends;

- Assist the Board in its oversight of the Company's risk management in areas affecting or relating to R&D, technology and intellectual property of the Company;

- Assist the Board and management on the overall intellectual property strategy of the Company;

- Review new technology in which the Company is, or is considering, investing;

- ***Meet with management to review the efficacy and safety profile of new products before they are launched by the Company***;

- Assist the Board and management in scientific and R&D aspects and relevant business implications of the Company's acquisitions, transactions and other business development activities; and

- Review and make recommendations on such other topics as deemed appropriate.

SUBSTANTIVE ALLEGATIONS

32. The Company was originally formed under the laws of the State of Delaware in November 2003 under the name Kinex Pharmaceuticals, LLC. In December 2012, the Company converted to a Delaware corporation, Kinex Pharmaceuticals, Inc. In August 2015, the Company restated its certificate of incorporation to change its name to Athenex, Inc.

33. According to the Company's recent public statements, the Company is a "global clinical stage biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer." The Company is organized around three platforms, including (1) an Oncology Innovation Platform; (2) a Commercial Platform; and (3) a Global Supply Chain Platform.

MATERIALLY FALSE AND MISLEADING STATEMENTS

34. On August 7, 2019, the Company issued a press release reporting that "Oral Paclitaxel and Encequidar had a Significantly Higher Response Rate Over IV Paclitaxel in a Phase III Pivotal Study in Metastatic Breast Cancer." This release provided:

[A]nnounced topline data showing that oral paclitaxel and encequidar (Oral Paclitaxel) met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase III pivotal study in metastatic breast cancer.

A total of 402 typical metastatic breast cancer patients were enrolled in a 2 to 1 ratio of Oral Paclitaxel to IV paclitaxel in the ITT population (265 in the Oral Paclitaxel group versus 137 in the IV paclitaxel group). Patient demographics were balanced in the two treatment groups. The primary efficacy endpoint was overall tumor response rate (ORR) confirmed at two consecutive timepoints using RECIST v1.1 criteria. Blinded assessments of tumor response were made by two independent radiologists and an independent adjudicator, using a computer algorithm to assign responses.

Oral Paclitaxel showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with an ORR of 36% for the Oral Paclitaxel group compared to 24% for IV paclitaxel patients based on ITT analysis ($p = 0.01$). Oral Paclitaxel also showed statistically significant improvement compared to IV paclitaxel based on other analyses on populations excluding non-evaluable patients (which would give higher response rates), with p-values ≤ 0.01 in all analyses. In addition, the results showed that the proportion of confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group.

Based on the data cut-off on July 25, 2019, there was a strong trend in progression free survival ($p = 0.077$) favoring Oral Paclitaxel over IV paclitaxel, and a strong trend in overall survival ($p = 0.11$) favoring Oral Paclitaxel over IV paclitaxel. At the cut-off date, a higher proportion of patients on Oral Paclitaxel compared with IV paclitaxel remained progression-free and Athenex expects the PFS and OS trend will continue to improve upon follow-up.

In the study, the Oral Paclitaxel group had lower incidence and severity of neuropathy compared to IV paclitaxel: 57% of IV paclitaxel patients experienced neuropathy (all grades) versus 17% of Oral Paclitaxel patients, with grade 3 neuropathy observed in 8% of IV paclitaxel patients versus 1% of Oral Paclitaxel patients. The results also showed lower incidence of alopecia, arthralgia and myalgia in the Oral Paclitaxel group. The incidence of neutropenia was similar in both groups, but there were more incidents of grade 4 neutropenia and infection in the Oral Paclitaxel group. There were also more gastro-intestinal side effects in the Oral Paclitaxel group.

Dr. Rudolf Kwan, Chief Medical Officer of Athenex, stated, “This is the second successful Phase III clinical program accomplished by the clinical team this year. We are excited by the positive results in the Phase III pivotal study, demonstrating improved ORR for Oral Paclitaxel compared to IV paclitaxel across a full spectrum of analyses and lower incidence of neuropathy in the Oral Paclitaxel group. We will

> be preparing our NDA submission as soon as possible. We are also investigating additional indications for Oral Paclitaxel as well as combinations with other anti-cancer drugs, including biologics and immuno-oncology drugs. With a longer duration of response observed in this trial, we will look into the potential of this drug candidate in metronomic dosing and maintenance therapy. Based on these results, we will aggressively advance the other oral chemotherapy programs."
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> Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex, commented, "Based on the results of the Phase III study, together with the preliminary results generated in the angiosarcoma study, Athenex believes that Oral Paclitaxel has the potential to represent a new class of oral anti-cancer drugs, if approved, based on the findings from this Phase III study showing statistically significant improvement in ORR as monotherapy and longer duration of response over IV paclitaxel, as well as strong trends in improved PFS and OS in patients with metastatic breast cancer. There is also evidence of early onset of activity in angiosarcoma. Adding to this potential are the favorable safety data from this study showing lower incidence of neuropathy, which is currently a major reason for discontinuing IV paclitaxel treatment. There is a potential for Oral Paclitaxel, which is not designed to require steroid pre-medication for immunosuppression, to serve as a cornerstone in chemotherapy in combination with other small molecule anti-cancer drugs, biologics, and immuno-oncology treatment approaches, including other drug candidates in our oncology pipeline."

35. On August 7, 2019, the Company held a conference call with analysts. On this call, Defendant Lau stated: "I'm pleased to provide an update on Athenex' second quarter operating results and, very importantly, to be able to share with you today the positive top line results achieved in our Phase III trial of oral paclitaxel and encequidar, also known as oral paclitaxel in metastatic breast cancer." Defendant Lau continued:

> [T]he highlights that our Phase III study successfully met its primary endpoint, showing a statistically significant and clinically meaningful improvement versus IV paclitaxel. We also saw evidence of potential benefits in terms of progression-free survival as well as overall survival.
>
> Taken together with oral paclitaxel's improved safety profile, which had lower incidence of neuropathy compared to IV paclitaxel, we believe, if approved, we will have a new class of anti-oral anticancer drugs with a differentiated and competitive profile.
>
> The successful outcome in this trial is a potentially transformative event for Athenex. We are currently analyzing the full dataset, but we believe that we are supportive of an NDA filing in metastatic breast cancer. We plan to request a pre-

> NDA meeting as soon as possible and plan to present the data at a major upcoming scientific meeting.

36. On this same call, Defendant Kwan stated: "As a reminder, we announced in January last year the FDA previously provided positive feedback to Athenex that they would accept the results of this one pivotal trial for license application in the U.S. if the primary endpoint is met. Importantly, these positive pivotal trial results add to a growing body of clinical evidence supporting oral paclitaxel and encequidar, which is characterized by high response rates and a strong safety profile."

37. On September 9, 2019, the Company participated in a call with analysts at the Morgan Stanley Healthcare Conference. On this call, Defendant Lau stated: "NDA, pre-NDA meeting will occur very soon. NDS is scheduled to be early next year for submission. Everything is on track. I think one thing I'm very proud of our team is that everything that we put forward in the last many years with regard to time-line, we actually delivered everything according to time line. We will be able to deliver NDA on schedule."

38. On November 7, 2019, the Company issued a press release on Form 8-K with the SEC announcing third quarter 2019 financial results and providing a corporate update. In this release, the Company stated that the anticipated NDA submission for Oral Paclitaxel was "on track."

39. In the Form 10-Q that this press release accompanied, the Company stated:

> In August 2019, we announced topline data showing that oral paclitaxel and encequidar ("Oral Paclitaxel") met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase III pivotal study in metastatic breast cancer.
>
> A total of 402 typical metastatic breast cancer patients were enrolled in a 2 to 1 ratio of Oral Paclitaxel to IV paclitaxel in the intent-to-treat ("ITT") population (265 in the Oral Paclitaxel group versus 137 in the IV paclitaxel group). Patient demographics were balanced in the two treatment groups. The primary efficacy

> endpoint was overall tumor response rate (ORR) confirmed at two consecutive timepoints using RECIST v1.1 criteria. Blinded assessments of tumor response were made by two independent radiologists and an independent adjudicator, using a computer algorithm to assign responses. Oral Paclitaxel showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with an ORR of 36% for the Oral Paclitaxel group compared to 24% for IV paclitaxel patients based on ITT analysis ($p = 0.01$). Oral Paclitaxel also showed statistically significant improvement compared to IV paclitaxel based on other analyses on populations excluding non-evaluable patients (which would give higher response rates), with p-values ≤ 0.01 in all analyses. In addition, the results showed that the proportion of confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group.
>
> Based on the data cut-off on July 25, 2019, there was a strong trend in progression-free survival ($p = 0.077$) favoring Oral Paclitaxel over IV paclitaxel, and a strong trend in overall survival ($p = 0.11$) favoring Oral Paclitaxel over IV paclitaxel. At the cut-off date, a higher proportion of patients on Oral Paclitaxel compared with IV paclitaxel remained progression-free.
>
> In the study, the Oral Paclitaxel group had lower incidence and severity of neuropathy compared to IV paclitaxel: 57% of IV paclitaxel patients experienced neuropathy (all grades) versus 17% of Oral Paclitaxel patients, with grade 3 neuropathy observed in 8% of IV paclitaxel patients versus 1% of Oral Paclitaxel patients. The results also showed lower incidence of alopecia, arthralgia and myalgia in the Oral Paclitaxel group. The incidence of neutropenia was similar in both groups, but there were more incidents of grade 4 neutropenia and infection in the Oral Paclitaxel group. There were also more gastro-intestinal side effects in the Oral Paclitaxel group.

40. Also, on November 7, 2019, the Company held a call with analysts to discuss the third quarter 2019 financial results. On this call, Defendant Kwan stated:

> We are moving ahead confidently towards our first NDA submission for our oral discovery platform based on the strong data we previously reported for our lead candidate, oral paclitaxel and encequidar. As a reminder, the randomized multicenter study involved 402 patients and compared our product to intravenous paclitaxel in patients with confirmed metastatic breast cancer and for whom paclitaxel monotherapy is recommended.
>
> We were very excited to announce that the study met its primary endpoint, showing statistically significant improvement over IV paclitaxel in confirmed overall tumor response rate based on ITT analysis, oral paclitaxel showed an overall response rate

> of 36% compared to 24% for IV paclitaxel patients. This endpoint was based on the RECIST 1.1 criteria with a p-value of 0.01. There was also benefit in terms of duration of response.
>
> As we detailed on our last call, we also saw strong trends for both progression-free survival and overall survival that favored oral paclitaxel. We are also very pleased neuropathy compared to IV paclitaxel, 17% versus 57% overall, and for grade free neuropathy, 1% versus 8%. Neuropathy is the major dose limiting toxicity for IV paclitaxel treatment and can be chronic and irreversible.
>
> Collectively, the results of this pivotal study represent an important milestone in the development of this new class of oral anti-cancer drugs. Based on the Phase III results, we see compelling evidence in terms of the efficacy and safety of oral paclitaxel's clinical benefit for patients with metastatic breast cancer. We believe it will be competitive and has the potential to become a cornerstone in the treatment of metastatic breast cancer.
>
> As we disclosed, we are scheduled to deliver an oral presentation of our Phase III results at the San Antonio Breast Cancer Symposium on December 13. We plan to share additional information around the top line efficacy and safety results that we reported in August. We believe the physician community will find the data compelling and look forward to this important update.
>
> In the meantime, we are currently working diligently to complete our NDA submission for oral paclitaxel, which we currently expect in the first quarter of next year. We expect to provide another update after the NDA has been filed.

41. On December 13, 2019, the Company announced "Superior Response and Survival with Lower Neuropathy of a Novel Oral Paclitaxel versus IV Paclitaxel in Treatment of Metastatic Breast Cancer." This release provided that Athenex was going to present these results in an oral presentation at the 2019 San Antonio Breast Cancer Symposium. In this press release, Defendant Kwan stated:

> Oral paclitaxel and encequidar is the first oral taxane to demonstrate in a Phase III study statistically significant improvement in response rate and median overall survival compared to IV paclitaxel, in the treatment of metastatic breast cancer while associated with a much lower incidence and severity of neuropathy. We believe these data suggest the potential for oral paclitaxel and encequidar to provide an important advance in the management of patients with metastatic breast cancer.

42. Also, on December 13, 2019, the Company published a copy of its presentation

from the San Antonio Breast Cancer Symposium entitled "Oral paclitaxel with encequidar (OPE): The first orally administered paclitaxel shown to be superior to IV paclitaxel on confirmed response and survival with less neuropathy: A Phase III clinical study in metastatic breast cancer."[4] In this presentation, the Company represented that the Primary Objectives of the study were: (i) "Efficacy Endpoint (Prescribed mITT Population)," with a "Confirmed tumor response by week 19," which was confirmed by "Blinded and adjudicated central independent review," and (ii) "Safety and Tolerability." The presentation further detailed the "Patient Selection and Analysis Populations" used in the study.

43. In conclusion, this presentation provided that "Oral paclitaxel and encequidar is the first oral taxane in a Phase III trial to demonstrate a significant improvement in confirmed overall response rate compared to IV paclitaxel." It further noted that "oral paclitaxel and encequidar was associated with improved overall survival in the modified intent-to-treat population" and "was associated with a lower incidence of neuropathy and alopecia." In sum, the Company stated that "Oral paclitaxel and encequidar provides an important oral therapeutic option for patients with metastatic breast cancer, representing a meaningful improvement in the clinical profile of paclitaxel."

44. On February 27, 2020, the Company issued a press release announcing its fourth quarter and full year 2019 financial results and providing a corporate update. In this release, the Company reported that "Oral Paclitaxel NDA submission is on track; Final FDA meeting scheduled for early April." This release further provided that the "[r]esults presented at 2019 San Antoni Breast Cancer Symposium . . . showed that Oral Paclitaxel had superior response and overall survival benefit compared to IV paclitaxel in the treatment of metastatic breast cancer,"

4 https://www.sec.gov/Archives/edgar/data/1300699/000119312519313917/d837714dex991.htm.

and that "[i]ncidence and severity of neuropathy were less frequent with Oral Paclitaxel compared to IV paclitaxel."

45. Also, on February 27, 2020, the Company held an earnings call with analysts to discuss its fourth quarter and full year 2019 financial results. On this call, Defendant Lau stated:

> We are delighted to share that we have already submitted an NDA to the FDA. We will share more information once we have confirmation that the application has been accepted. Our partner, Almirall, is responsible for the regulatory filing in Europe and will be managing commercial activities in both the U.S. and Europe.
>
> The planned NDA submission for oral paclitaxel is supported by a strong clinical data package, including the results of our Phase III trial in metastatic breast cancer completed in 2019. This trial successfully met its primary efficacy end point, showing a statistically significant improvement on overall response rate for oral paclitaxel compared to IV paclitaxel. We'll provide an update on the trial at the San Antonio Breast Cancer Symposium in December, also announcing in the conference that oral paclitaxel demonstrated a significant improvement in overall survival.
>
> I would note that this is the first oral taxane to demonstrate a significant improvement in response rate and overall survival in a Phase III study with much less neuropathy. We are on track to submit a NDA in the U.S. for oral paclitaxel.

46. On April 9, 2020, the Company announced that it "recently participated in a constructive meeting with the [FDA] as scheduled, to discuss the clinical section of the [NDA] for oral paclitaxel and encequidar for the treatment of metastatic breast cancer. The Company is on track to submit the NDA in accordance with the FDA's guidance, and will provide a further update when the FDA's official response to the filing becomes available."

47. On May 7, 2020, the Company issued a press release announcing financial results for the first quarter of 2020, ended March 31, 2020, and providing a corporate update. In this release, Defendant Lau stated that "the NDA for Oral Paclitaxel is on track to be submitted soon," stating that the product had a "strong clinical data package[s]."

48. Also, on May 7, 2020, the Company held an earnings call with analysts to discuss

Athenex's first quarter 2020 financial results. On this call, Defendant Kwan stated that the pre-NDA filing "meeting [with the FDA] was very constructive, and we did receive the meeting minutes, and the submission is on track based on the feedback the FDA provide [*sic*] to us." Defendant Kwan continued:

> Our NDA submission for oral paclitaxel is imminent. We had a productive FDA meeting in early April, where we discussed our clinical package. We have been in active dialogue with the agency, and this meeting represent one of the final steps as we prepare for submission. We will provide an update on the FDA's official response when the submission becomes available.
>
> In our meeting with the FDA, the agency also provided us with guidance on further assessment of survival endpoints, and we will communicate further when it's appropriate. In addition to the strong clinical data seen in the Phase III study of Oraxol in metastatic breast cancer, we have several ongoing studies of oral paclitaxel in additional indications, including combinations.

49. On August 6, 2020, the Company held a call with analysts to discuss the Company's second quarter 2020 financial results. On this call, Defendant Lau stated:

> Regarding the NDA for oral paclitaxel, we will be picking the same approach as we did with tirbanibulin ointment and plan to make an official announcement, once the filling has been accepted by the FDA. We are obviously pleased here with the excellent work conducted by our clinical and regulatory teams and the execution on both of these products. We look forward to providing a further update soon. Our commercial team is putting all the key elements in place for successful oral paclitaxel launch. Our goal as we have preciously said, is to make oral paclitaxel be chemotherapy of choice for metastatic breast cancer. And we hope to build on the success of this initial indication that expands into the compelling opportunities that exist in other cancer. Mr. Tim Cook, our head of marketing will provide further details on our commercial initiative later on in this call. We have strengthened our balance sheet through additional financings. Use of proceeds will include the commercial launch of oral paclitaxel as well as ongoing pipeline development and manufacturing infrastructure. Having the strong balance sheet is important in providing the financial flexibility to further invest in the life cycle management of oral paclitaxel and additional R&D activities in order to maximize the potential value of our product pipeline. Dr. Rudolf Kwan will provide more details on this shortly. Our specialty pharma business is performing and we reported today, record $40.2 million in revenue from product sales in the second quarter, an increase of 82% year-over-year, this represents our highest quarterly product sales to date, as a result we're raising our product sales guidance for this full year 2020 to at least mid-teen percentage growth year-over-year from $80.5 million in 2019.

50. On September 1, 2020, the Company issued a press release announcing that the FDA had accepted for filing the Company's U.S. NDA for Oral Paclitaxel and Encequidar in metastatic breast cancer with priority review. This release provided that:

> [Athenex] announced that the [FDA] has accepted for filing the Company's [NDA] for oral paclitaxel and encequidar (Oral Paclitaxel) for the treatment of metastatic breast cancer and has granted the application Priority Review. The FDA grants Priority Review to applications for potential drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of February 28, 2021. Additionally, the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.
>
> "We are working diligently with the FDA on this Priority Review to bring Oral Paclitaxel to patients with metastatic breast cancer as quickly as possible," said Dr. Rudolf Kwan, Chief Medical Officer of Athenex. "Intravenous (IV) Paclitaxel is a foundational chemotherapy in multiple tumor types and we plan to invest in broadening the label and uses for Oral Paclitaxel."
>
> Dr. Johnson Lau, Chairman and Chief Executive Officer of Athenex, also stated, "We are delighted to have achieved this major milestone for Athenex. We continue to finalize our commercial preparations to ensure a successful launch of Oral Paclitaxel, if approved. We see Oral Paclitaxel as a potentially important alternative to IV infusions, especially during the current pandemic, as it may allow cancer patients to take the oral chemotherapy at home. We believe the Oral Paclitaxel program validates our broader Orascovery platform, and we are committed to applying the technology to convert other IV chemotherapies into oral agents."
>
> The Oral Paclitaxel NDA submission is supported by data from a single pivotal Phase III study of Oral Paclitaxel for the treatment of metastatic breast cancer. The study is a randomized, controlled clinical trial designed to compare the safety and efficacy of Oral Paclitaxel monotherapy versus IV paclitaxel monotherapy. As previously reported, the study achieved its primary endpoint showing statistically significant improvement in overall response rate, along with a lower neuropathy, for Oral Paclitaxel compared to IV Paclitaxel.

51. One week later, on September 8, 2020, the Company published a presentation as an

attachment to a Form 8-K filing with the SEC.[5] In this presentation, the Company stated that its NDA submission was "based on data from Phase III pivotal study – a randomized, controlled clinical trial designed to compare the safety and efficacy of Oral Paclitaxel monotherapy versus IV Paclitaxel monotherapy for the treatment of metastatic breast cancer." This presentation further provided that this study "Met Primary ORR Endpoint," meaning that it had "Statistically Significant Improvement in ORR Compared to IV Paclitaxel."

52. Also, on September 8, 2020, the Company participated in a Special Call with analysts. On this call, Defendant Kwan stated:

> I'm extremely delighted to report that the NDA for oral paclitaxel has been accepted for filing by the U.S. FDA. The application has been granted priority review and assigned a PDUFA target action date of February 28, 2021. Priority review, as a reminder, is granted to applications for potential therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment when compared to standard applications. In addition, the FDA indicated in its letter that it does not currently plan to hold an Advisory Committee meeting. We are very pleased with the outcome and look forward to continue working closely with the agency in the review process. This submission is supported by a single Phase III pivotal trial, comparing the safety and efficacy of oral paclitaxel head-to-head with IV paclitaxel.
>
> I would like to quickly recap some of the positive highlights from our Phase III study. We presented the data at the 2019 San Antonio Breast Cancer Symposium. The study met its primary endpoint, showing that oral paclitaxel had a statistically significant improvement in overall response rate compared to IV paclitaxel. We show here the responses for both ITT as well as prespecified modified ITT populations, both of which were statistically significant. Importantly, we also demonstrated an overall survival benefit in the mITT population with a median of 27.9 months for oral paclitaxel versus 16.9 months for IV paclitaxel, an impressive 11-month improvement, which was statistically significant.

53. Also, on this September 8, 2020 call, Defendant Lau stated: "[w]ith clinical success demonstrated and an NDA now filed in the first indication, we believe the development and regulatory risks have been largely mitigated."

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5 https://www.sec.gov/Archives/edgar/data/1300699/000119312520240630/d21816dex992.htm.

54. Moreover, on September 8, 2020, the Company filed a Prospectus on Form 424B5 with the SEC announcing its intent to sell 10 million shares of the Company's common stock, pursuant to a previously-filed shelf registration statement. In this Prospectus, the Company stated:

> On September 1, 2020, we announced that the [FDA] has accepted for filing our [NDA] for Oral Paclitaxel for the treatment of metastatic breast cancer ("MBC"), and has granted the application Priority Review. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of February 28, 2021. Additionally, the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.
>
> We announced topline results in August 2019 for our Phase 3 study of Oral Paclitaxel for the treatment of MBC and presented further data of the Phase 3 study in an oral presentation at the 2019 San Antonio Breast Cancer Symposium, or SABCS, in December 2019. Results demonstrated that the study met its primary endpoint showing statistically significant improvement in overall response rate for Oral Paclitaxel compared to intravenous ("IV") paclitaxel and neuropathy was less frequent with Oral Paclitaxel compared to IV paclitaxel. In addition, ongoing analysis of secondary endpoints of survival showed a strong trend favoring Oral Paclitaxel. In particular, Oral Paclitaxel showed a statistically significant improvement in overall survival compared to IV paclitaxel in the prespecified modified intention-to-treat population.

55. Two days later, on September 10, 2020, the Company announced that it was offering 10 million shares at $11.00 each in this public offering, and further granted the underwriters a 30-day option to purchase up to an additional 1.5 million shares at $11.00 each.

56. On November 5, 2020, the Company reported its financial results for its third quarter of 2020, ended September 30, 2020. In a press release attached to a Form 8-K filed with the SEC, the Company reiterated that the "FDA accepted and granted priority review of NDA for Oral Paclitaxel in metastatic breast cancer," and highlighted how the Company had "[f]our abstracts featuring Oral Paclitaxel . . . accepted for presentation at the San Antonio Breast Cancer Virtual Symposiums, to take place December 8-11, 2020."

57. In this November 5, 2020 release, Defendant Lau stated:

> Our [NDA] filing for Oral Paclitaxel was accepted with priority review and a target action date of February 28, 2021 . . . . Oral Paclitaxel has a compelling efficacy, and tolerability profile that we believe positions it to potentially become the chemotherapy of choice in metastatic breast cancer. Our supply chain is in place and we are finalizing our commercial plans, with the goal of launching in the U.S. upon approval in the first quarter of 2021.

58. Also, on November 5, 2020, the Company held a call with analysts to discuss its third quarter financial results. On this call Defendant Kwan stated: "the NDA for Oral Paclitaxel was accepted by the FDA and assigned a PDUFA target action date of February 28, 2021. Ongoing dialogue with the FDA is encouraging and we are pleased with our progress to date."

59. On this same November 5, 2020 call, Defendant Cook stated:

> The final stages of commercial planning for Oral Paclitaxel are underway. The company is prepared to launch immediately upon the FDA action date of February 28, 2021 or earlier. Let me recap our progress.
>
> Our medical science liaison team is in place and is engaging in scientific discussions with key opinion leaders. Our nurse oncology educators are on board and will provide information on dosing and managing side effects to the oncology treatment teams upon launch. In the meantime, the team will begin profiling its local territories and start having unbranded discussions around the disease state and patient care.
>
> We have hired 2 national account directors to engage with the payer community during the third quarter. Based on the Preapproval Information Exchange Act or PIE, the account managers may target payers establishing policy at a national level ahead of drug approval. Activities focused on educating these customers about health care economic information pertaining to Oral Paclitaxel in order to facilitate coverage decisions and budget allocations. Athenex is in the process of hiring 5 corporate account directors to cover smaller regional payers and large integrated delivery networks like Kaiser.
>
> Our last step involves onboarding our sales representatives in the December-January time frame ahead of our expected launch. In parallel, we are wrapping up our work on the value proposition of Oral Paclitaxel to the payer community and finalizing our pricing and contracting strategy. Feedback has been overwhelmingly positive as payers view our drug as innovative, which is in line with our prior pricing assumptions. Contracts are in place with all key distributors and specialty pharmacies, and our distribution model is finalized.

> Developing patient outreach initiatives remain a key focus. Our patient support program is near completion. An additional point of contact is created in the specialty pharmacy hub to help manage both treatment and reimbursement as well as to provide a financial assisted system for patients.
>
> October was breast cancer awareness month. Athenex has been very active and focused on amplifying its share of voice and visibility around breast cancer through the month. The company launched a guide to facing metastatic breast cancer on October 9 and held a virtual media tour featuring Dr. Beth DuPree, which consisted of TV and radio interviews accompanied by social media post across multiple platforms.
>
> Core marketing messages to be used by our sales force are in the final stages of development. Our market research shows that our messages around efficacy and the first oral taxane resonate well. Physicians are responding positively to the safety language around neuropathy, no need to pre-medicate patients and a lack of infusion reactions.
>
> We will have a presence at the San Antonio Breast Cancer Symposium. In addition to the 4 abstracts that Rudolf mentioned, we will also have a virtual exhibit. Lastly, we finalized the brand campaign for Oral Paclitaxel that will roll out after launch.
>
> To summarize, we are ready to launch Oral Paclitaxel upon approval. Payer outreach has begun and we have prepared initiatives targeting physicians, office staff and patients. Additionally, we are planning several virtual physician outreach events that can be rapidly deployed upon approval to promote the drug.

60. On December 9, 2020, the Company issued a press release presenting "Updated Phase 3 Data on Survival and Tolerability Associated with Oral Paclitaxel and Encequidar in Patients with Metastatic Breast Cancer." The Company announced that data presented at the 2020 San Antonio Breast Cancer Symposium "indicate[s] benefits of oral paclitaxel and encequidar . . . versus IV paclitaxel (IVP) on Progress-Free Survival (PFS) and on Overall Survival (OS), which supports superiority on the primary endpoint Overall Response Rate (ORR)."

61. In this December 9, 2020 press release, the Company announced:

> The findings further support the superiority of increased ORR observed with oral paclitaxel. These data were presented today during a spotlight poster presentation at the 2020 San Antonio Breast Cancer Symposium (SABCS).

"Having previously presented superior efficacy on overall response rate and favorable tolerability versus IV paclitaxel at SABCS 2019, it is gratifying to report that our pivotal Phase 3 trial continues to show sustained efficacy and manageable adverse events with oral paclitaxel and encequidar," said Dr. Johnson Lau, Chairman and Chief Executive Officer of Athenex. "The updated Phase 3 PFS and OS data further support the clinical rationale for oral paclitaxel as an efficacious and tolerable treatment option for people living with metastatic breast cancer."

The spotlight poster presentation at SABCS featured an update on PFS and OS data from the Phase 3 trial. In the prespecified modified intent-to-treat (mITT) population (n = 360), the median PFS data showed a benefit for oral paclitaxel versus IVP (8.4 vs. 7.4 months, respectively; hazard ratio [HR] = 0.739; 95% confidence interval [CI]: 0.561, 0.974; p = 0.023). Median OS data also showed a benefit for oral paclitaxel versus IVP (23.3 months vs. 16.3 months, respectively; HR = 0.735; 95% CI: 0.556, 0.972; p = 0.026).

In the intent-to-treat (ITT) population, which included all 402 randomized patients, the median PFS showed a benefit for oral paclitaxel versus IVP (8.4 months vs. 7.4 months, respectively; HR = 0.768; 95% CI: 0.584, 1.01; p = 0.046). The median OS data demonstrated a trend favoring oral paclitaxel versus IVP (22.7 months vs. 16.5 months, respectively; HR = 0.794; 95% CI: 0.607, 1.037; p = 0.082).

Updated safety analyses of up to 112 weeks continue to demonstrate the reduction in incidence and severity of neuropathy favoring oral paclitaxel versus IVP: all grades of neuropathy were 22% vs. 64%, and grade 3 neuropathy was 2% vs. 15%. Also presented were data on the effect of prophylactic treatments on the incidence and severity of gastrointestinal-related adverse events. After approximately 30% of patients were enrolled, the Phase 3 trial protocol was amended to allow patients randomized to the oral paclitaxel arm to receive prophylactic pre-medications for gastrointestinal side effects. Overall gastrointestinal (GI)-related adverse events (AEs) were less frequent in the IV paclitaxel arm. GI-related AEs improved in the oral paclitaxel arm following the amendment, as measured by lower incidences of grade 2 vomiting before and after amendment (24% vs. 7%) and grade 2 diarrhea before and after amendment (27% vs. 16%).

"The oral paclitaxel regimen appears to overcome some of the limitations of IV therapy, particularly in terms of reducing the risk of neuropathy," commented lead investigator Gerardo Antonio Umanzor Fúnez, M.D., a medical oncologist at Centro Oncologico Integral, working with DEMEDICA of San Pedro Sula, Honduras. "The lessened burden of neuropathy, the ability to manage GI side effects with prophylactic treatments, and the convenience of home-based administration, could be transformational in the treatment of metastatic breast cancer, especially in the current environment."

Oral paclitaxel has been granted Priority Review by the [FDA] for the treatment of metastatic breast cancer with a PDUFA date of February 28, 2021.

About the Phase 3 Oral Paclitaxel and Encequidar Clinical Trial

> The Phase 3 trial randomized 402 patients with any metastatic breast cancer subtypes in a 2:1 ratio to receive either the oral paclitaxel regimen (205 mg/m2 of oral paclitaxel plus 15 mg of encequidar) for three days a week or the approved IV paclitaxel regimen (175 mg/m2) as a three-hour infusion every three weeks. The primary efficacy endpoint was overall response rate (ORR) confirmed at two consecutive timepoints by a blinded, independent radiology review that used RECIST v1.1 criteria to evaluate patients' tumors for response. The trial was designed to demonstrate superiority of oral paclitaxel over IVP on the primary end point of ORR. Secondary endpoints included progression-free survival (PFS) and overall survival (OS). The trial was not powered to demonstrate superiority of oral paclitaxel versus IVP on the secondary survival endpoints of PFS and OS. These secondary endpoints were not controlled for multiplicity. P-values presented are nominal.

62. The statements identified above were materially false and misleading and failed to disclose material facts about the Company's business, operations, and prospects. As discussed below, the Director Defendants misled investors and the Company's shareholders by misrepresenting and omitting to disclose: (i) the data included in the Oral Paclitaxel plus Encequidar NDA presented a safety risk to patients in terms of an increase in neutropenia-related sequalae; (ii) the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by BICR; (iii) the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR; (iv) that the Company's Phase 3 study that was used to file the NDA was inadequate and not well-conducted in a patient population with metastatic breast cancer representative of the U.S. population, such that the FDA would recommend a new such clinical trial; (v) as a result, it was foreseeable that the FDA would not approve the Company's NDA in its current form; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

THE TRUTH EMERGES

63. On March 1, 2021, the Company issued a press release entitled "Athenex Receives

FDA Complete Response Letter for Oral Paclitaxel Plus Encequidar for the Treatment of Metastatic Breast Cancer." In this release, the Company noted that the "FDA Issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form." This release further provided that "[i]n the CRL, the FDA indicated its concern of safety risk to patients in terms of an increase in neutropenia-related sequalae on the Oral Paclitaxel arm compared with the IV paclitaxel arm."

64. In this March 1, 2021 press release, the Company further stated that the "FDA also expressed concerns regarding the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by blinded independent centra review (BICR). The [FDA] stated that the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR."

65. Further, the Company wrote that the FDA "recommended that Athenex conduct a new adequate and well-conducted clinical trial in a patient population with metastatic breast cancer representative of the population of the U.S. The [FDA] determined that additional risk mitigation strategies to improve toxicity, which may involve dose optimization and/or exclusion of patients deemed to be at a higher risk of toxicity, are required to support potential approval of the NDA."

66. Also, on March 1, 2021, the Company issued a press release announcing fourth quarter and full year 2020 financial results.[6] In this press release, the Company reiterated that in its Complete Response Letter, the FDA expressed: (i) "[c]oncerns about safety risks associated with increase in neutropenia-related sequelae"; (ii) "[c]oncerns about the primary endpoint assessment conducted by the Blinded Independent Central Review (BICR)"; and (iii)

[6] https://ir.athenex.com/news-releases/news-release-details/athenex-provides-fourthquarter-and-full-year-2020-corporate-and.

"[r]ecommendation that Athenex conduct a new clinical trial in a patient population with metastatic breast cancer representative of the population in the U.S."

67. In this release, Defendant Lau stated: "[b]ased on the clinical benefits demonstrated by the Phase III trial results, we are committed to exploring our available options to obtain approval for oral paclitaxel and encequidar. Additionally, we will undertake a thorough review of our organization to best position ourselves to create value for all stakeholders as we move forward."

68. On this news, the price of the Company's shares plummeted from their February 26, 2021 closing price of $12.10 per share to a March 1, 2021 close of just $5.46 each. This represents a one-day drop of approximately 55%, or hundreds of millions of dollars in lost market capitalization.

DUTIES OF THE DIRECTOR DEFENDANTS

69. By reason of their positions as officers and/or directors of the Company, and because of their ability to control the business and corporate affairs of the Company, the Director Defendants owed the Company and its investors the fiduciary obligations of trust, loyalty, and good faith. The obligations required the Director Defendants to use their utmost abilities to control and manage the Company in an honest and lawful manner. The Director Defendants were and are required to act in furtherance of the best interests of the Company and its investors.

70. Each director of the Company owes to the Company and its investors the fiduciary duty to exercise loyalty, good faith, and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets. In addition, as officers and/or directors of a publicly held company, the Director Defendants had a duty to promptly disseminate accurate and truthful information regarding the Company's operations, finances, and financial condition, as well as present and future business prospects, so that the market price of the

Company's stock would be based on truthful and accurate information.

71. To discharge their duties, the officers and directors of the Company were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the affairs of the Company. By virtue of such duties, the officers and directors of the Company were required to, among other things:

(a) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

(b) conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's business prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;

(d) remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiries in connection therewith, take steps to correct such conditions or practices, and make such disclosures as necessary to comply with federal and state securities laws;

(e) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state and local laws, and rules

and regulations; and

(f) ensure that all decisions were the product of independent business judgment and not the result of outside influences or entrenchment motives.

72. Each Director Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Director Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Director Defendants were aware, or should have been aware, posed a risk of serious injury to the Company.

73. The Director Defendants breached their duties of loyalty and good faith by causing the Company to issue false and misleading statements concerning the business results and prospects of the Company. As a result, the Company has expended, and will continue to expend, significant sums of money related to investigations and lawsuits.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

74. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties and gross mismanagement by the Director Defendants.

75. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and retained counsel competent and experienced in derivative litigation.

76. During the illegal and wrongful course of conduct at the Company and to the

present, the Board consisted of Defendants Lau, Campbell, Davis, Fok, Kanfer, Spiegel, Tsang, Vierling and Wu. Because of the facts set forth throughout this Complaint, demand on the Company Board to institute this action is not necessary because such a demand would have been a futile and useless act.

77. The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

78. The Director Defendants (or at the very least a majority of them) cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. For the reasons that follow, and for reasons detailed elsewhere in this complaint, Plaintiff has not made (and should be excused from making) a pre-filing demand on the Board to initiate this action because making a demand would be a futile and useless act.

79. Each of the Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

80. Each of the Director Defendants authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

81. Additionally, each of the Director Defendants received payments, benefits, stock options, and other emoluments by virtue of their membership on the Board and their control of the

Company.

Defendant Lau

82. Because of his CEO management position with the Company, Defendant Lau is not independent.

83. The Company provides Defendant Lau with his principal occupation, and he receives handsome compensation for his services. Defendant Lau was responsible for most of the false and misleading statements and omissions that were made, including those contained in the Company's SEC filings referenced herein, many of which he either personally made or signed off on.

84. Defendant Lau is Defendant in the securities class actions entitled *Gupta v. Athenex, Inc., et al.*, Case 1:21-cv-00337 (W.D.N.Y.) and *Koza v. Athenex, Inc., et al.*, Case 1:21-cv-00413 (W.D.N.Y.) (the "Securities Class Action") and faces a substantial likelihood of liability; therefore, demand on Defendant Lau is futile.

85. Further, in June 2018, the Company entered into two in-licensing agreements with Avalon wherein the Company obtained certain intellectual property ("IP") from Avalon to develop and commercialize the underlying products. Under these agreements, the Company is required to pay upfront fees, future milestone payments, and sales-based royalties.

86. In June 2019, the Company entered into an agreement whereby Avalon will hold a 90% ownership interest and the Company will hold a 10% ownership interest of the newly formed entity under the name Nuwagen Limited ("Nuwagen"), incorporated under the laws of Hong Kong. Nuwagen is principally engaged in the development and commercialization of herbal medicine products for metabolic, endocrine, and other related indications. The Company contributed nonmonetary assets in exchange for the 10% ownership interest.

87. Defendant Lau, our Chief Executive Officer and Chairman, and Defendant Fok, collectively have a controlling interest in, and serve on the board of directors of, Avalon Global Holdings Limited, the indirect parent of Avalon BioMedical. As of December 31, 2020, Avalon held 786,061 shares of our common stock, which represented approximately 1% of our total issued shares for the period.

88. In addition, the Company has entered into a consulting agreement with Dr. Jane Fang, who is the wife of Defendant Lau, to provide consulting advice related to the development of our tirbanibulin (formerly known as KX-01) ointment, reporting to Defendant Kwan, the Company's Chief Medical Officer. The Company paid consulting fees of approximately $351,600 to Dr. Fang in 2020.

89. The prospect of doing more business with Dr. Fang (Defendant Lau's wife) casts a bit of doubt on his disinterestedness.

Defendant Kwan

90. The Company receives certain clinical development services from ZenRx Limited and its subsidiaries ("ZenRx"), a company for which Defendant Kwan serves on the board of directors ZenRx. ZenRx is a contract research company located in New Zealand. ZenRx conducts certain clinical development with us and we have entered into a license agreement with ZenRx. In connection with such services, the Company made payments to ZenRx of $0.6 million for the year ended December 31, 2020.

91. The prospect of doing more business with ZenRX (a company in which Defendant Kwan is a board member) casts a bit of doubt on his disinterestedness.

Defendants *Kanfer, Tsang and Wu*

92. Defendants Kanger, Tsang & Wu served as members of the Audit Committee. As

such, they are responsible for the effectiveness of the Company's internal controls, the integrity of its financial statements, and its compliance with laws and regulations. In their capacities as Audit Committee members, Kanger, Tsang & Wu reviewed and approved the disclosures regarding the Company's business performance and future projections. As alleged herein, Defendants Kanger, Tsang & Wu failed to ensure the integrity of the Company's internal controls, allowing the materially misleading statements to be disseminated in the Company's SEC filings and other disclosures. Thus, the Audit Committee Defendants breached their fiduciary duties and are not disinterested, and demand is excused as to them.

Defendants Spiegel, Fok, Vierling and Wu

93. Defendants Spiegel, Fok, Vierling and Wu served as members of the Scientific and Products Committee. As such, they are responsible for, among other things, meeting with management to review the efficacy and safety profile of new products before they are launched by the Company. As alleged herein, Defendants Spiegel, Fok, Vierling and Wu knew or were reckless in not knowing (i) the data included in the Oral Paclitaxel and Encequidar New Drug Application ("NDA") presented a safety risk to patients in terms of an increase in neutropenia-related sequalae; (ii) the uncertainty over the results of the primary endpoint of objective response rate ("ORR") at week 19 conducted by blinded independent central review ("BICR"); (iii) the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR; (iv) Athenex's Phase 3 study that was used to file the NDA was inadequate and not well-conducted in a patient population with metastatic breast cancer representative of the U.S. population, such that the FDA would recommended a new such clinical trial; (v) as a result, it was foreseeable that the FDA would not approve Athenex's NDA in its current form; and (vi) as a result, the Company's public statements were materially false and misleading.

COUNT I

(Against Defendants Lau, Kwan And Cook For Violations Of Sections 10(b) And 21D Of The Exchange Act)

94. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

95. The Company and certain officers of the Company are named as defendants in the Securities Class Action, which assert claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Actions for these violations of law, the Company's liability will be in whole or in part due to Defendants Lau, Kwan and Cook's willful and/or reckless violations of their obligations as officers and directors of the Company, especially in connection with their breach of their duties as members of the Audit Committee.

96. Moreover, through their positions of control and authority as officers of the Company, Defendants Lau, Kwan and Cook were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of the Company, including the wrongful acts described in the Securities Class Actions and herein.

97. As such, Defendants Lau, Kwan and Cook are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

COUNT II

(Against The Director Defendants For Breach Of Fiduciary Duty)

98. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

99. The Director Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Director Defendants owed the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

100. The Director Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

101. The Director Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Director Defendants breached their fiduciary duties of loyalty and good faith by permitting the use of inadequate practices and procedures to guide the truthful dissemination of Company news to the investing public and to the Company's shareholders, allowing or permitting false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise failing to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

102. As a direct and proximate result of the Director Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

103. As a direct and proximate result of the Director Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs associated with defending and/or settling securities lawsuits and governmental investigations, severe damage to the share price of the Company's stock, resulting in an increased cost of capital, and reputational harm.

COUNT III

(Against The Director Defendants For Waste Of Corporate Assets)

104. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

105. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the time period in issue. It resulted in continuous, connected, and ongoing harm to the Company.

106. As a result of the misconduct described above, the Director Defendants wasted corporate assets by, *inter alia*: (a) paying excessive compensation, bonuses, and termination payments to certain of its executive officers; (b) awarding self-interested stock options to certain officers and directors; and (c) incurring potentially millions of dollars of legal liability and/or legal costs to defend and/or settle actions addressing Defendants' unlawful actions.

107. As a result of the waste of corporate assets, the Director Defendants are liable to the Company.

108. Plaintiff, on behalf of the Company, has no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Against all Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of Defendants' breaches of fiduciary duties;

B. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect the Company and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the

Company's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;

C. Awarding to the Company restitution from Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by Defendants;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff demands a trial by jury on all issues so triable.

Dated: June 3, 2021

BIELLI & KLAUDER, LLC

/s/ Ryan M. Ernst
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